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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,456	01/21/2005	Albertina Maria Eduarda Arien	JAB1715-US-PCT	4146
27777	7590	01/23/2009	EXAMINER	
PHILIP S. JOHNSON			AHMED, HASAN SYED	
JOHNSON & JOHNSON				
ONE JOHNSON & JOHNSON PLAZA			ART UNIT	PAPER NUMBER
NEW BRUNSWICK, NJ 08933-7003			1615	
			MAIL DATE	DELIVERY MODE
			01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,456	ARIEN ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 October 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2 and 12-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/19/08</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Receipt is acknowledged of applicants': (a) amendment, which was filed on 28 October 2008 and (b) IDS, which was filed on 19 November 2008.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 12-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,716,203 ("Casey").

Casey teaches a diblock polymer comprising:

- the polymer block A (first block) comprising a linear pharmaceutically acceptable hydrophilic polymer (polyalkylene oxide) of instant claim 1 (see col. 1, lines 8-9);
- the polymer block B (second block) comprising at least two different monomers selected from the group listed therein (glycolic acid and trimethylene) of instant claims 1 and 2 (see col. 1, lines 10-11);
- the diblock copolymer liquid at a temperature below 50°C of instant claim 1 (see col. 2, lines 23-26);
- the diblock copolymer liquid at a temperature below 37°C of instant claim 15 (see col. 2, lines 23-26).

Casey explains that the disclosed diblock polymers are useful as hydrogels in a pharmaceutical composition (see col. 1, lines 39-41).

Casey does not explicitly teach polymer block A with a molecular weight < 1,000 of instant claim 1 or the diblock molecular weights of instant claims 12-14 however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable polymer weight through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant weight ranges.

Casey teaches a polymer block A of 5 to 25 percent by weight of the copolymer (see col. 1, lines 45-47). Furthermore, the disclosed viscosity (see col. 2, lines 24-26) suggests a diblock polymer weight similar to that being claimed as viscosity is a function of polymer weight.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a diblock polymer comprising a linear, hydrophilic polymer block A and a polymer block B comprising at least two different monomers, as

taught by Casey. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful hydrogels for pharmaceutical compositions, as explained by Casey.

* * * * *

Response to Arguments

Applicants' arguments filed on 28 October 2008 have been fully considered but they are not persuasive.

1. Applicants argue that, “[o]ne skilled in the art could not have predicted that such relatively small copolymers would be able to form stable micelles based on the disclosure of Casey.” See remarks, page 5.

It is noted that the feature upon which applicants rely (i.e., stable micelles) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

2. Applicants argue that, “...one skilled in the art would not have been able to predict that micelles formed from such "small" copolymers could still incorporate drugs.” See remarks, page 5.

Examiner respectfully submits that applicants are not claiming incorporation of the copolymer into drugs. Furthermore, applicants are not claiming a weight requirement for polymer block B. As such, the claims allow the hydrophobic polymer to be from 1000 to 9000 MW, which is a very broad range, rather than the “relatively

specified molecular weight" applicants suggest (see remarks, page 5, section II, 3rd paragraph).

3. Applicants argue, "...one skilled in the art could not have predicted that the copolymers could very easily incorporate drugs..." See remarks, page 5.

Examiner respectfully submits that incorporation into drugs was not claimed.

4. Applicants argue, "Casey does not disclose or suggest that the block copolymers therein have self-emulsifying properties that can form spontaneously stable micellar solution in water..." See remarks, page 5.

Again, examiner respectfully submits that self-emulsifying properties were not claimed; only a diblock polymer was claimed.

5. Applicants argue, "Casey disclosed merely the viscosity of a 0.5% solution of the copolymer in chloroform or methylene chloride, not that the copolymer itself is liquid."
See remarks, page 6.

Examiner respectfully disagrees. The cited passage begins, "[t]he inherent viscosity of the copolymer...", suggesting that the viscosity disclosed is that of the copolymer itself.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615